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| 29157 | 7590 | 11/16/2010 | EXAMINER | |
| K&L Gates LLP | | | MI, QIUWEN | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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| | | | |
|------------------------------|--------------------------------------|------------------------------------|--|
| Office Action Summary | Application No. 10/598,909 | Applicant(s) WANG ET AL. | |
| | Examiner QIUWEN MI | Art Unit 1655 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 November 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 9-11 and 15-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 12-14, 20 and 21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's amendment filed on 11/5/2010 is acknowledged. Claims 1-21 are pending. Claims 9-11, and 15-19 are withdrawn as they are directed toward non-elected invention groups. **Claims 1-8, 12-14, 20, and 21 are examined on the merits.**

Any rejection that is not reiterated is hereby withdrawn.

Claim Rejections –35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-8, 12-14, 20, and 21 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Osanai (JP 09107880 A), in view of Edenharder et al (Edenharder et al, Isolation and characterization of structurally novel antimutagenic flavonoids from spinach (*Spinacia oleracea*), Journal of agricultural and food chemistry, (2001 Jun) Vol. 49, No. 6, pp. 2767-73), Faulks et al (Faulks et al, Kinetic of gastro-intestinal transit and carotenoid absorption and disposal in ileostomy volunteers fed spinach meals, Eur J Nutr (2004) 43: 15-22), and Hovari et al (Hovari et al, Examination of flavonoid content in Hungarian Vegetables, Special Publication - Royal Society of Chemistry (1999), 240(Natural Antioxidants and Anticarcinogens

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in Nutrition, Health and Disease), 296-298), and further in view of Imazawa et al (JP 2003164261 A).

This rejection is maintained for reasons of record set forth in the Office Action mailed out on 5/5/2010, repeated below. Applicants' arguments filed have been fully considered but they are not deemed to be persuasive.

Osanai teaches to produce a suitably producible cow's milk (thus milk from animal origin, thus a carrier) at a low cost by using a widely used vegetable, capable of enriching iron, enhancing hematopoietic actions, further containing various vitamins or minerals blended in good balance and effective against various symptoms of anemia, constipation or climacteric disturbance of women (thus a food, thus an oral composition). This cow's milk contains a vegetable and is obtained by adding about 12.5 g KOMATSU-NA [*Brassica campestris* (rapa group)], about 2.5 g spinach (thus a vegetable, thus a leave), about 2.5 g total amount of mulukkiyya, parsley, water cress and beefsteak plant, 22.5 g lemon (thus a fruit) and 2.5 g reducing palatinose with about 150cc cow's milk. Furthermore, the cow's milk containing the vegetable is prepared by placing about 12.5 g KOMATSU-NA, about 2.5 g spinach and about 2.5 g total amount of mulukkiyya, parsley, water cress and beefsteak plant based on 10 cc cow's milk in a mixer, pulverizing (thus milling in milk) and mixing the ingredients, adding about 22.5 g lemon and about 2.5 g reducing palatinose thereto and further adding cow's milk thereto so as to make the sum total to 200 cc (thus a liquid, thus a miscible primary composition) (see Abstract). Osanai teaches a method of producing cowsmilk containing vegetables characterized as placing approximately 15 g of carrots, approximately 22.2 g of lemon, and approximately 2 g of reduced palatinose in 100 cc of cowsmilk in a mixer, pulverizing it and mixing it, straining it

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in a strainer twice (thus excluding insoluble fibers), and then adding cowsmilk to this so that it reaches 200 cc (page 5, claim 6 of the full translation).

As evidenced by Edenharder et al, spinach contains carotenoids (thus a hydrophilic bioactive component) and flavonoids such as flavonol and flavanone (thus a lipophilic bioactive component) (see Abstract), therefore, the milk product of Osanai that contains spinach contains at least essential lipophilic and hydrophilic bioactive components consisting of vegetable etc.

As further evidenced by Faulks et al, spinach contains beta-carotene (thus a hydrophilic bioactive component) (see Abstract).

As also evidenced by Hovari et al, the highest quercetin concentration could be detected in different types of onion (67.1-171.3 mg/kg) and in spinach (page 296, last paragraph) (thus the limitation of claim 21 is met).

Osanai does not teach the insoluble fibers are removed by centrifuging the carrier after milling.

Imazawa et al teach a method for manufacturing extract and/or squeezed liquid, involves grinding raw material, homogenizing, dispersing in medium at less than 60 degrees C, extracting, emulsifying and removing dregs and/or squeezed dregs. The raw materials are selected from coffee, green tea (thus containing lipophilic and hydrophilic bioactive components), black tea, oolong tea, herb tea, wild grass tea, chinese medicine tea , cocoa, vanilla, fruits or vegetables. The dispersion medium has low temperature of less than 50 degrees C preferably -5-50 degrees C. The dispersion medium is water, cow's milk (thus a carrier) dairy products, liquid of saccharides, sugar alcohol, mineral, vitamin, stabilizer, emulsifier and bacteriostatic. The mixture is homogenized using homogenous machine (thus milling the material) equipped with pump,

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which pours dispersion liquid at high voltage and high speed continuously in the homogenous valve (see Abstract). Imazawa et al also teach in accordance with a conventional method, separation removal of extraction slag and/or the juice slag is carried out using a liquid cyclone, a clarifier, centrifugal separation (thus insoluble fibers are removed by centrifuging the carrier after milling), filtration, precision filtration, decantation etc [0027] (see machine translation attached). Imazawa et al teach the method is suitable for the continuous mass production and extremely effective from the viewpoint of the effective utilization of food resources and the economic merit compared with conventional extraction/squeezing method (see Abstract).

First of all, the MPEP states the following: "[E]ven though product-by-process claims are limited by and defined by the process determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process...The product-by-process claim was rejected because the end product, in both the prior art and the allowed process, ends up containing metal carboxylate. The fact that the metal carboxylate is not directly added, but is instead produced in-situ does not change the end product" (see MPEP 2113 [R-1]). Therefore, although Osanai teaches using strainers twice, instead of using claimed centrifuging process, insoluble fibers are being removed either way, and the final products are not materially different. Even if there is subtle difference between using strainers and centrifuge machine, it would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to use the claimed centrifuging step since Imazawa et al teach removing extraction slag by a liquid cyclone, a clarifier, centrifugal separation, filtration, precision

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filtration, or decantation. It is evidenced by Imazawa et al that centrifuging step is well known in the art to remove extraction slags, and it is used interchangeably in the art with other methods such as filtration or straining. Since Imazawa et al teach using dispersion medium cowsmilk to grind raw plant material for extraction, and since Imazawa et al teach the method is extremely effective in utilization of food resources and has economic merit compared with conventional extraction/squeezing method, one of the ordinary skills in the art would have been motivated to combine the teachings of the references together.

From the teachings of the references, it is apparent that one of the ordinary skills in the art would have had a reasonable expectation of success in producing the claimed invention.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

Applicant argues that “*Osanai* is entirely directed to cow's milk containing vegetables whose main constituent is rapa gourd, wherein the vegetable containing rapa gourd is mixed with cowsmilk. See, *Osanai*, pages 5-6. *Edenharder* is entirely directed to the isolation and characterization of antimutagenic flavonoids from spinach. See, *Edenharder*, Abstract. Indeed, the entire disclosure of *Edenharder* is directed to the purification of antimutagens from spinach by preparative and micropreparative HPLC from a methanol/water extract of dry spinach after removal of lipophilic compounds. See, *Id.* As such, not only is the subject matter of *Edenharder* nonanalogous art when compared to *Osanai* and the present claims, but *Edenharder* teaches away from the present claims when *Edenharder* discloses removal of lipophilic compounds from the spinach extract. Similar to *Edenharder*, *Faulks* is entirely directed to the quantification of [3-

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carotene and lutein absorption from a representative green vegetable with different degrees of processing, using both mass balance and metabolic modeling of triglyceride-rich lipoprotein plasma fraction. See, *Faulks*, Summary. Like *Edenharder*, the green vegetable of *Faulks* is spinach and the entire disclosure is directed to the kinetics of gastro-intestinal transit and carotenoid absorption and disposal in ileostomy volunteers fed spinach meals. See, *Faulks*, Summary and Introduction. As such, *Faulks* is also nonanalogous art when compared to *Osanai* and the present claims. *Hovari* is entirely directed to the effects of flavanoids on human health and the content of flavonoids in specific vegetables. See, *Hovari*, Introduction, Table 1. *Imazawa* is entirely directed to extraction efficiency and preparation of juice in a short time for industrialization. See, *Imazawa*, paragraphs 18 and 19. *Imazawa* is entirely directed to processes that include pulverizing the coffee beans, fruits, vegetables, etc., adding a dispersing media to the pulverized coffee beans, fruits, vegetables, etc., and then homogenizing the mixture. See, *Imazawa*, Working Examples. As such, the cited references are clearly directed to unrelated products or processes that have completely different objectives. Moreover, none of the cited references even recognizes the benefits obtained from the presently claimed compositions including, for example, improved bioavailability and miscibility from extracted fruits or plant materials by milling the material in a milk or milk protein-containing carrier and centrifuging the milk or milk protein-containing carrier after milling of the fruit or plant materials to remove the insoluble fibers. Such treatments allow the essential lipophilic and hydrophilic bioactive components to have improved bioavailability and miscibility in the milk or milk protein-containing carrier. See, specification, page 4, lines 1-3” (page 9, 2nd paragraph to page 10, 2nd paragraph).

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This is not found persuasive. The rejection is based on Osanai in view of Imazaawa, references Edenharder et al, Faulks et al, and Hovari et al are only brought in to show the intrinsic properties of the product in Osanai. Osanai teaches “the cow's milk containing the vegetable is prepared by placing about 12.5 g KOMATSU-NA, about 2.5 g spinach and about 2.5 g total amount of mulukkiyya, parsley, water cress and beefsteak plant based on 10 cc cow's milk in a mixer, pulverizing (thus milling in milk) and mixing the ingredients” (see Abstract). The process of mixing the claimed ingredient with milk in a mixer, pulverizing, and mixing the ingredient is not materially different from the claimed “milling the material in the milk or milk protein-containing carrier”. Although Osanai teaches using strainers twice, instead of using claimed centrifuging process, insoluble fibers are being removed either way, and the final products are not materially different. Even if there is subtle difference between using strainers and centrifuge machine, it would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to use the claimed centrifuging step since Imazawa et al teach removing extraction slag by a liquid cyclone, a clarifier, centrifugal separation, filtration, precision filtration, or decantation. It is evidenced by Imazawa et al that centrifuging step is well known in the art to remove extraction slags, and it is used interchangeably in the art with other methods such as filtration or straining. Since Imazawa et al teach using dispersion medium cowsmilk to grind raw plant material for extraction, and since Imazawa et al teach the method is extremely effective in utilization of food resources and has economic merit compared with conventional extraction/squeezing method, one of the ordinary skills in the art would have been motivated to combine the teachings of the references together.

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Applicant argues “Further, if the proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there exists no reason for the skilled artisan to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984). In fact, Applicants submit that what the Patent Office has done here is to apply hindsight reasoning by attempting to selectively piece together teachings of each of the references in an attempt to recreate what the claimed invention discloses. Indeed, the skilled artisan must have a reason to combine the cited references to arrive at the present claims. Applicants respectfully submit that such a reason is not present in the instant case” (page 10, 3rd paragraph).

In response to Appellant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the Appellant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Applicant's arguments have been fully considered but they are not persuasive, and therefore the rejections in the record are maintained.

Conclusion

No claim is allowed.

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THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Qiuwen Mi whose telephone number is 571-272-5984. The examiner can normally be reached on 8 to 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Qiuwen Mi/

Primary Examiner, Art Unit 1655